IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
ETHICON WAVE 4 CASES LISTED IN EXHIBIT A	JUDGE GOODWIN

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF SARAH ABBIE COLLINS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude general opinions of Sarah Abbie Collins, M.D. (Doc. 3605).

INTRODUCTION

Dr. Collins practices urogynecology in Chicago with the Northwestern Medicine Department of Obstetrics and Gynecology Division of Female Pelvic Medicine and Reconstructive Surgery. Ex. C to Pl's motion, Curriculum Vitae at 1. She is double board certified in Female Pelvic Medicine and Reconstructive Surgery, and Obstetrics and Gynecology. *Id.* Dr. Collins has published seventeen articles about urogynecology topics in peer-reviewed publications, she reviews articles for multiple urology/urogynecology journals, and she has served on the Clinical Guidelines Committee of the American Urogynecologic Society. *Id.* at 1; Ex. B to Pl's motion, Expert Report at 2; Ex. Ex. A hereto, 3/6/17 Dep. 58:3-64:17.

Over the course of her career, Dr. Collins has performed hundreds of gynecologic surgeries, including female pelvic floor reconstruction, using a number of products and

techniques, such as native tissue repair, Burch colposuspension, and midurethral slings. Ex. B to Pl's motion, Expert Report at 3-4. She has implanted approximately 600 polypropylene midurethral slings, including TVT and TVT-Exact. Ex. A hereto, 3/6/17 Dep. 27:11-15, 29:20-23, 33:3-23, 40:6-41:17.

Dr. Collins teaches other surgeons about these devices. She serves as an Assistant Professor of Obstetrics and Gynecology and Urology with Northwestern Medicine, and she previously served as Assistant Professor of Obstetrics and Gynecology with University of Chicago Medicine from 2011 to 2016. Ex. C. to Pl's motion, Curriculum Vitae at 1. Dr. Collins has also made numerous academic presentations throughout the country. *Id.* at 2-4.

In these cases, Dr. Collins intends to offer opinions generally addressing the utility and safety of Ethicon's TVT device.[1] Her opinions are based upon her education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other materials. Ex. B to Pl's motion, Expert Report. In their motion, Plaintiffs have made vague challenges to certain aspects of Dr. Collins's opinions. Plaintiffs' challenges are not tied to the opinions actually offered by Dr. Collins in her report, but instead, are generic and regurgitated from Plaintiffs' challenges of Ethicon's other experts. Dr. Collins is well-qualified to offer the opinions set forth in her report, her opinions are supported by a reliable methodology, and Plaintiffs' challenges lack merit.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

[1] In her report, Dr. Collins also provides general opinions about TVT-Exact. In this wave of cases, however, Ethicon has designated Dr. Collins to testify only in cases in which a Plaintiff was implanted with a TVT device

I. The Court should allow Dr. Collins to offer opinions about warnings.

Without citing a single opinion set forth in Dr. Collins's expert report, Plaintiffs make a generic challenge to Dr. Collins's ability to testify about warnings and claim that she bases her opinions only on her own clinical practice and experience. Dr. Collins has opined that the TVT instructions for use ("IFU") was sufficient, that "[t]he IFU document may serve as a cursory overview of the information [surgeons] are expected to master about the device," that surgeons are expected to learn about the device and potential risks from other sources (such as training and literature), and that the risks of incontinence surgeries is "commonly known to surgeons" regardless of the IFU. Ex B to Pl's motion, Expert Report at 4, 19-20; Ex. A hereto, 3/6/17 Dep. 121:6-7, 122:15-21, 324:11-325:6.

Dr. Collins will opine on the completeness and accuracy of the IFU warnings from a clinical perspective based on her knowledge of and clinical experience with these devices. Plaintiffs do not challenge Dr. Collins's clinical expertise. Instead Plaintiffs argue that she is not qualified to opine on the adequacy of the IFUs because she lacks familiarity with the regulatory process governing the development of such documents. Plaintiffs cite only to Dr. Collins's responses to specific deposition questions without linking that testimony directly to any of Dr. Collins's actual warning opinions set forth in her expert report.

Ethicon concedes that Dr. Collins is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings, however, Dr. Collins, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). Indeed, Dr. Collins's report and deposition testimony detail her extensive experience with these devices, including particular risks and

complications she has experienced and researched, and her report explains her opinions in detail. *E.g.*, Ex. B to Pl's Motion, Expert Report at 16-26.

Plaintiffs do not appear to challenge Dr. Collins's competency to testify that risks that did not appear on the IFUs were already commonly known to clinicians. *Compare In re: Ethicon*, 2016 WL 4582231, at *3 n. 2 (finding that Plaintiffs had not challenged this issue). To the extent that their motion is construed as doing so, any such challenge should be denied. Dr. Collins will testify that the complications that Plaintiffs' experts claim should have been in the IFUs: (a) are risks that pelvic surgeons commonly know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. *E.g.*, Ex. B to Pl's Motion, Expert Report at 4; Ex. A hereto, 3/6/17 Dep. 117:4-118:2, 174:12- 176:9. As it relates to the latter two categories, Dr. Collins' opinions are based on her extensive clinical experience, as well as her thorough critique of scientific literature. *See, e.g.*, Ex. B to Pl's Motion, Expert Report at 16-26; *see also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12 (S.D. W.Va. Apr. 28, 2015).

Moreover, Dr. Collins, as an experienced clinician and educator, is well qualified to testify about complications that are "commonly known" such that they need not be included in an IFU. Ex. B to Pl's Motion, TVT Report at 4, 18. The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability § 2 cmt. j (1998); Restatement (Second) of the Law of Torts § 402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21

CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Collins is certainly competent to share her opinions about what risks should be obvious to surgeons who use the devices and how a clinician skilled in the art of pelvic floor surgery would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Collins. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law. In fact, Dr. Collins has special expertise to testify about these matters because she teaches others about these risks. Ex B to Pl's motion, Expert Report at 2.

Finally, Plaintiffs suggest that the Court should limit Dr. Collins's warning opinions, because the 2015 version of the TVT IFU is the only rendition that she definitively remembered reviewing.[2] Plaintiffs do not show that this has any bearing on Dr. Collins's overarching opinion that it was not necessary for the IFU to include risks that were commonly known. To the extent that Plaintiffs take issue with Dr. Collins's warning opinions, they may pursue those issues on cross-examination.

[2] Dr. Collins testified that she has reviewed a prior rendition, but she could not definitively remember when it was released. Ex. A hereto, 3/6/17 Dep. 120:3-15, 330:3-331:13. Dr. Collins has experience reviewing IFUs from Ethicon as well as various other manufacturers. Ex B to Pl's motion, Expert Report at 4.

II. The Court should allow Dr. Collins to provide certain design and scientific property opinions.

Despite Dr. Collins's elite qualifications as a urogynecologist, Plaintiffs argue that she is not competent to provide opinions about the "design and scientific properties of the TVT." (Doc. 2607, p. 6). Once again, Plaintiffs' argument is vague and generic, and Plaintiffs do not cite to any portion of Dr. Collins's report. For instance, in support of their argument that she "arbitrarily offers opinions regarding the properties of polypropylene used in Ethicon mesh products," Plaintiffs cite Dr. Collins's entire report. *Id.* at 6 & n. 22. The Court should deny Plaintiffs' motion for lack of specificity and otherwise determine that Dr. Collins is competent to render opinions that may touch upon design and scientific properties.

A. "Design" Opinions

Plaintiffs assert that, though she allegedly has a "lack of education, experience, training, and knowledge about the design process of polypropylene devices, Dr. Collins attempts to opine on the design, including weight and porosity, of the TVT and TVT-Exact mesh devices." *Id.* at 8. Other than referencing the mesh weight and porosity, however, Plaintiffs do not specify what design opinions that they seek to preclude Dr. Collins from offering. Dr. Collins does not intend to provide design process or product development opinions. To the extent that her opinions touch upon the weight and porosity of the mesh, those are not design opinion and she is qualified to offer them. As noted by Dr. Collins, she is a design expert only from a clinical perspective. *See* Ex. A hereto, 3/6/17 Dep 125:4-12, 222:3-16, 311:9-16.

In rejecting a similar challenge to one of Ethicon's other urogynecologist experts, Dr. Michael Woods, the Court noted that Plaintiffs' motion is "plagued with confusion about what constitutes a design opinion," and found that "Dr. Woods has not expressed any opinions about

the process of designing a product." *In re: Ethicon*, 2016 WL 4582231, at *3. As with that case, the Court should deny Plaintiffs' challenge as "moot." *Id.*

Dr. Collins's background, including her extensive clinical experience and review of the medical literature, certainly enable her to provide expert opinions that touch upon the weight and porosity of the PROLENE mesh used in TVT. Dr. Collins explained in her report and her deposition the basis for her opinions that the mesh is of appropriate weight and porosity. Ex. B to Pl's motion, Expert Report at 24; Ex. A hereto, 3/6/17 Dep. 126:9-133:20, 303:21-304:20. For instance, in discounting Plaintiffs' unsupported theory that lighter-weight, larger pore mesh would serve as a safer alternative, Dr. Collins relied on her personal experience in stating as follows:

> A. No, I think when you're talking about the efficacy of a midurethral sling, my sense of what's required of the material is based on my experience of having placed these and then taking care of patients who have them implanted.
>
> And I have used the ultra-lightweight meshes in sacral colpopexy before and have found them to be prohibitively flimsy. They've torn during handling in the operating room and that concerns me with respect to function.
>
> Obviously you don't want to place any material into a patient if it's not going to help them.
>
> And I believe that a really large pore size would probably not be able to accomplish the task of creating a good supportive scaffold for the urethra at the midpoint the way the midurethral sling is supposed to.
>
> Q. And have you tested that theory?
>
> A. I feel like my clinical experience satisfies my curiosity about that, but I've never conducted an experiment.
>
> I have handled ultra-lightweight meshed at the time of sacral colpopexy and have found them to be frustratingly flimsy.

Id. at 132:20-133:30

As it relates to pore size, she further testified: "I mean, there is so much clinical evidence and peer-reviewed literature to suggest that the pore size is exactly right. If we were concerned about the pore size being too small, then by definition we would be seeing a lot of infected mesh and the truth is we're just not seeing that. Clinically, I haven't seen it. I don't think I've ever been able to definitively say that a Type 1 polypropylene mesh is infected." *Id.* at 198:3-11. Dr. Collins also noted that the medical literature has not attributed any complications to inadequate pore size. *Id.* at 302:13-17. For all of these reasons, Dr. Collins explained that "[a]t this time, there is no clinical evidence that another polymer, such as PVDF, would produce the same excellent results in terms of cure rates, patient satisfaction, low complications, and surgeon acceptance, which has been proven time and time again with the TVT and similar polypropylene midurethral slings." Ex. B to Pl's motion, Expert Report at 11.

At the same time that Plaintiffs suggest that Dr. Collins is not competent to testify about mesh pore size and weight, Plaintiffs attempt to elicit expert opinions from their own urogynecologists with similar experiences based on these precise same subjects. If Plaintiffs are correct that this is an area beyond Dr. Collins's expertise, then this is also an area beyond the expertise of each of Plaintiffs' urogynecologist experts.

B. "Properties" Opinions

Plaintiffs next argue that, because she is not a biomaterials expert or polymer chemist, Dr. Collins is not competent to testify about properties of the TVT device, "such as degradation, inertness, weight, density, porosity, and cut (laser or mechanical) of the polypropylene mesh." (Doc. 3607, p. 9). The Court has consistently found similar challenges to be "without merit" and noted that the Defendants' urogynecologist experts' "extensive clinical and research experience qualifies [them] to opine on mesh's reaction to and effect on the human body, and relatedly, the

safety and efficacy of mesh products." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 45493666, at *3 (S.D.W. Va. Aug. 25, 2016); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4556807, at *4 (S.D.W. Va. Aug. 31, 2016).

Dr. Collins's opinions about degradation and other mesh properties are set forth on pages 20-26 of her report. Ex. B to Pl's motion. Her opinions are not at the molecular level and the equivalent of the opinions of polymer scientist, but instead, focused on clinical aspects of alleged degradation. *See Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *20 (S.D. W. Va. May 5, 2015) ("That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level'"). In these MDLs, the Court has allowed urologists and gynecologists with similar qualifications as Dr. Collins to testify about degradation and other issues touching upon properties. For instance, in *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *45 (S.D. W. Va. Apr. 28, 2016), the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's produces for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualified

> him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.
>
> * * *
>
> The literature on which Dr. Douso relies includes multiple studies regarding polypropylene mesh devices and on the body's post-operative reaction to the mesh.
>
> The court has permitted physicians in related cases to offer similar opinions based on their clinical experience and review of the scientific literature. *See Tyree*, 54 F. Supp. 3d at 585 (finding an expert's "clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion"). Accordingly, I **FIND** that Dr. Douso's extensive clinical experience and literature review provide a sufficient reliable basis for his opinions. The plaintiff's motion on this point is **DENIED**.

2016 WL 1718836, at *46 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 550, 585 (S.D.W. Va. 2014) (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9.

In Section II.A above, Ethicon set forth Dr. Collins's well-reasoned explanations for her opinions about weight, density, and porosity. During her deposition, Dr. Collins explained that her opinions about the inertness of the mesh is based on her clinical experience as well as her

review of the medical literature, particularly the Thames report. Ex. A hereto, 3/6/17 Dep. 207:15-208:9; *see also* Ex. B to Pl's motion, Expert Report at 11.

As it relates to the cutting of the mesh, Dr. Collins has explained that "[w]hether the TVT is mechanically cut or laser cut is clinically insignificant and a difference between the two has not been demonstrated by any reliable clinical trials." Ex. B to Pl's motion, Expert Report at 20. *See also* Ex. A hereto, 3/6/17 Dep. 295:20-296:1. Dr. Collins's background, experience, and review of the literature render her well qualified to testify that TVT is safe and effective regardless of the manner by which the mesh is cut.

Plaintiffs accuse Dr. Collins of "ignor[ing] a large body of evidence" related to these issues (Doc. 3607, p. 11), but the only "evidence" that they identify that she supposedly disregarded was flimsy anecdotal information. Dr. Collins reviewed an extensive amount of medical literature, did not cherry-pick, and explained why she discounted certain studies. Ex. B to Pl's motion, Expert Report; Ex. A hereto, 3/6/17 Dep. 152:6-157:12. Plaintiffs' primary complaint is that Dr. Collins did not find Ethicon internal documents to be particularly probative.[3] But, Dr. Collins explained why such anecdotal information means very little and pales in comparison to the "really robust scientific literature about these devices [that] is almost overwhelming in quantity." *Id.* at 139:4-19. As noted by Dr. Collins, "I just can't imagine that one [internal company] memo would change what I already know based on a systematic review type level evidence," and she observed that she is unaware of "any physicians who rely as part of

[3] Dr. Collins did review the reports of Plaintiffs' experts, Drs. Rosenzweig and Ostergard, which referenced a number of Ethicon documents and depositions, but they did not change her opinions. *Id.* at 299:17-300:13.

their practice on internal company e-mails with respect to making decisions about which products they're going to employ."[4] *Id.* at 140:13-15, 323:17-22. *See also id.* at 139:20-141:8.

Indeed, Plaintiffs' position is inconsistent with this Court's recognition that "internal Ethicon documents" generally "are not sufficiently reliable scientific bases under *Daubert.*" *Bellew v. Ethicon, Inc.*, 2014 WL 12685965, at *9 (S.D.W. Va. Nov. 20, 2014). Plaintiffs were free to present Dr. Collins with any specific internal company documents during her deposition and ask her questions about those documents, but they chose not to do so. This is a matter more appropriately handled through cross-examination.

There is similarly no merit to Plaintiff's criticism that Dr. Collins discounted the Material Safety Data Sheet ("MSDS") for raw polypropylene. Dr. Collins explained, for instance, that the MSDS is not even applicable to the PROLENE mesh in TVT, because PROLENE includes antioxidant additives. *Id.* at 207:7-14, 210:8-212:9. As noted by Dr. Collins: "I mean I think the Thames paper is irrefutable, and I have that data. So, I'm not sure there is anything that I could read from an internal document from Ethicon that would change my mind about that." *Id.* at 210:2-6.[5]

In sum, the Court should reject Plaintiffs' vague and generic challenge to Dr. Collins's opinions that may touch upon design or properties. Dr. Collins only intends to provide opinions that fall well within her experience and qualifications as a urogynecologist. To the extent that Plaintiffs intend to nitpick any of her opinions, they may do so through cross-examination.

[4] Thus, Plaintiffs essentially criticize Dr. Collins for failing to employ in the courtroom a different standard than what she and other physicians employ in their professional practice.

[5] Dr. Collins also remarked that, based on her extensive review, she did not find "any evidence that there are any adverse events or complications reported in the literature related to cytotoxicity. *Id.* at 309:5-11.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' motion to exclude Dr. Collins's opinions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this day, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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